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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,044	09/11/2003	Subhra Chakrabarti	078200-0305447	8318

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EXAMINER	
PHAM, AUDREY S	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,044	CHAKRABARTI ET AL.	
	Examiner	Art Unit	
	Audrey S. Pham	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SAO

DETAILED ACTION

Re: Chakrabarti *et al.*

Claims 1-84 are pending.

Note: Claim 40 lacks proper dependency because Claim 40, which depends from Claim 1, does not further limit Claim 1. Alternatively, Claim 40 lacks a proper antecedent basis because it is unclear which limitations the term " the composition" referenced. For the purpose of including Claim 40 in the restriction groupings, it was assumed that Claim 40 refers to the composition of Claim 38.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, 38-42, 44 drawn to an isolated human monoclonal antibody designated RM4, a composition, a pharmaceutical composition, and a kit thereof, classified in class 530, subclass 387.1.

II. Claims 24-32, 38-40, 43 drawn to an isolated human antibody designated RM2, a kit and a pharmaceutical composition thereof, classified in class 530, subclass 387.1.

III. Claims 33-37, drawn to a nucleic acid and a cell, classified in class 536, subclass 23.1.

IV. Claim 45, drawn to a method of producing an antibody, classified in class 435, subclass 69.1.

V. Claims 46-51, drawn to an *in-vitro* method of detecting the presence of AgRM4, classified in class 435, subclass 7.1.

VI. Claims 46-51, drawn to an *in-vivo* method of detecting the presence of AgRM4, classified in class 435, subclass 9.1.

VII. Claim 52, drawn to a method of identifying an inhibitor of AgRM4 expression, classified in class 435, subclass 4.

VIII. Claims 53-83 drawn to a method of inhibiting the proliferation of a cell that expresses AgRM4, classified in class 424, subclass 130.1.

IX. Claim 84, drawn to a method of screening for the presence of a hyperproliferative disorder in a subject comprising contacting the tissue *in vitro* with a RM4 antibody and assaying for the presence of AgRM4, classified in class 435, subclass 500.

X. Claim 84, drawn to a method of screening for the presence of a hyperproliferative disorder in a subject comprising contacting the tissue *in vivo* with a RM4 antibody and assaying for the presence of AgRM4, classified in class 435, subclass 500.

The inventions are distinct, each from the other for the following reasons:

The inventions of groups I-III and the methods of groups IV-X are related as products and processes of use. The inventions can be shown to be distinct if one or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case, the nucleic acid molecule, as claimed, can each be used in a materially different process such as in methods of developing binding assays, methods of purification, or methods of making said molecules. Likewise, the antibodies, as claimed, can each be used

in materially different methods such as in methods of developing vaccines, methods of treating cancer or methods of developing a therapeutic inhibitor.

The inventions of groups I-III encompass multiply distinct and independent products that encompass different functional as well as structural formulas. Groups I-II encompass antibodies and group III encompasses a nucleic acid molecule. The antibodies include, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Furthermore, the antibody of each group has a distinct function and a specific binding target that is unique to that antibody. Each of these groups represents a separate and distinct product which is made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Further, the search for antibodies, or polynucleotides, or small organic molecules that potentially inhibit the numerous and wide variety of target genes as listed would invoke a high burden of search as each target gene is structurally and functionally unrelated. Searching the inventions of each group would impose an undue burden because a search of one group would not be used to determine the patentability of the other groups. Because a different search in the literature would be required and the issue of patentability would be considered separately, a group is patentability distinct.

The inventions of groups IV-X are materially distinct methods, which differ at least in objectives, method steps and reagents. Group V is drawn to a method of making an antibody, with an objective different from the other groups. Groups V-VI are drawn to, respectively an *in-vitro* and *in-vivo*, method of detecting AgRM4. Group VII is drawn to identifying an inhibitor. Group VIII is drawn to a method of inhibiting the proliferation a cell. Groups IX-X are drawn to, respectively *in-vitro* and *in-vivo*, methods of screening for the presence of a hyperproliferative disorder. Each of the groups employs chemically distinct reagents to accomplish the various objectives. Searching all of the groups with all of the different reagents, steps or objectives would invoke a high burden of search.

These inventions are distinct for the reasons given above and they have acquired separate statuses in the art as shown by their different classifications. The search required for one group is not required for the other groups and vice versa. For these reasons, restriction for examination purposes as indicated is proper.

Species Election

The above invention groups each contain multiple generic claims which include a plurality of alternatively usable substances or members. These alternative limitations are independent or distinct inventions such that they do not share a common utility or share a substantial structural feature disclosed as being essential to that utility. Because they are not so closely related, a search and examination of the entire claim cannot be made without undue burden. The members of the alternative groupings are described in the following:

Groups I and II (Claims 14 and 29) each is generic to a plurality of disclosed patentably distinct species comprising the following cytotoxic molecules: bacterial toxin, plant toxin, radionuclide, cytotoxic drug or cytokine.

Groups I, II, V-VI (Claims 17, 32, 49) each is generic to a plurality of disclosed patentably distinct species comprising the following detectable labels: radioisotope, fluorescent compound, colloidal metal, chemiluminescent compound, bioluminescent compound, enzyme or paramagnetic label.

Groups I and VIII (Claims 20-22 and 56-58) each is generic to a plurality of disclosed patentably distinct species comprising the following hyperproliferating cells: metastatic breast, metastatic colon, metastatic gut, metastatic lung, non-metastatic breast, non-metastatic colon, non-metastatic gut, non-metastatic lung. The hyperproliferating cells of the above species represent separate and distinct conditions that differ at least in etiology, pathophysiology, and immunobiology. As such, each species would require different searches and the consideration of different patentability issues.

Group VIII (Claims 54-55) is generic to a plurality of disclosed patentably distinct species comprising the following proliferating cells: brain, lung, skin, pancreatic. The cells of the above species represent separate and distinct products with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group VIII (Claim 71) is generic to a plurality of disclosed patentably distinct species comprising the following tumor stages: I, II, III, IV or V. The tumor stages of the above species represent separate and distinct condition with different etiology, pathophysiology and immunobiology such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Group VIII (Claims 72-76) is generic to a plurality of disclosed patentably distinct species comprising the following tumors: solid, liquid, breast, colon, gut, lung, hematopoetic, metastatic, non-metastatic, sarcoma, carcinoma, melanoma, myleloma, blastoma, lymphoma, and leukemia. The tumor of the above species represent separate and distinct condition with different etiology, pathophysiology and immunobiology such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Groups IX-X (Claim 84) each is generic to a plurality of disclosed patentably distinct species comprising the following hyperproliferative disorders: breast, colon gut, lung, brain, skin or pancreas. The disorders of the above species represent separate and distinct conditions with different etiology, pathophysiology and immunobiology such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Upon election of any one of the above groups, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoining Claims

NOTE:

The Examiner has required restriction between product and process claims. Where Applicant elects claim(s) directed to a product and the product claim(s) is/are subsequently found allowable, the withdrawn process claim(s) that depend(s) from or otherwise include all the limitations of the allowable product claim(s) will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if an amendment is presented prior to a final rejection or allowance, whichever is earlier. Amendment submitted after final rejection is governed by 37 CFR 1.116; amendment submitted after allowance is governed by 37 CFR 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claim(s) and process claim(s) may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the withdrawn process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship Amendment

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended to be in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request, as set forth in 37 CFR 1.48(b), and by a processing fee, as set forth in 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Audrey S. Pham whose telephone number is (571) 272-3323. The Examiner can normally be reached during the hours of 8:30 AM - 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached during business hours at the telephone number: (571) 272-0787. The fax number for the organization, where this application or proceeding is assigned, is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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